



This document is scheduled to be published in the Federal Register on 07/06/2016 and available online at <http://federalregister.gov/a/2016-15898>, and on [FDsys.gov](http://FDsys.gov)

BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Government-Owned Inventions; Availability for Licensing**

AGENCY: National Institutes of Health, HHS.

ACTION: Notice

SUMMARY: The invention listed below is co-owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION, CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Shark Antibodies that Target Tumor and Viral Antigens

Description of Technology:

Shark V-NAR (Variable New Antigen Receptor) antibodies are an emerging class of therapeutic candidates. As single domain (heavy chain) antibodies with an extensive antigen-binding repertoire, shark V-NAR antibodies may provide advantages over traditional antibodies. Specifically, the smaller size of shark V-NAR antibodies may provide increased solubility, thermal stability, refolding capacity, and the ability to recognize epitopes that are sterically hindered from recognition by larger antibodies, but without loss of specificity in antigen-binding.

Researchers at the National Cancer Institute's Laboratory of Molecular Biology (NCI LMB) have developed an immunological platform that includes the development of a shark V-NAR antibody phage display library, isolation of specific antibodies that bind to several tumor and viral antigens from the library, and the development of the specific antibodies for treatment of cancer or viral infection. Specific antibody targets for binders include tumor-specific antigens (GPC3 [*Clone F1*], PD1 [*Clone A1*], HER2 [*Clones A6/A7*]), and viral antigens (MERS [*Clones A3, A7, A8, B4, and B5*] and SARS [*Clone O1*]).

Anti-glypican 3 (GPC3) V-NAR, Clone F1, is an antibody of immediate interest since it has already shown specific binding to GPC3-expressing tumor cells *in vitro*. Thus, anti-GPC3 V-NAR represents a viable candidate for development of an antibody-toxin/drug conjugate (ADC and immunotoxin), a bispecific antibody or a chimeric antigen receptor (CAR) against GPC3-expressing tumor cells.

#### Potential Commercial Applications:

- Therapeutic Uses
  - Use as unconjugated antibodies
  - Use as targeting moieties for immunoconjugates such as CARs, ADCs, Immunoconjugates, bispecific antibodies, etc.
- Diagnostic agent for detecting and monitoring target-expressing malignancies

#### Value Proposition:

- Potential to be first to market with high specificity and binding to targets resulting in less non-specific cell killing, therefore fewer potential side-effects for the patient
- Small size of antibodies enhances stability, solubility, and target recognition

#### Development Stage:

- *In-vitro* data – Shark/Human anti-GPC3 chimera can bind to GPC3-positive tumor cells
- *In-vivo* testing

#### Inventor(s):

Mitchell Ho (NCI), *et al.*

#### Intellectual Property:

US Provisional Application 62/334,194 (HHS Reference No. E-113-2016/0-US-01) filed May 10, 2016 entitled “Variable New Antigen Receptor (VNAR) Antibodies and Antibody Conjugates Targeting Tumor and Viral Antigens”

Collaboration Opportunity: Researchers at the NCI seek parties interested in licensing or co-developing shark V-NAR antibodies and/or conjugates for cancer therapeutics and/or diagnostics.

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D.  
email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov)

Date: June 28, 2016

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[FR Doc. 2016-15898 Filed: 7/5/2016 8:45 am; Publication Date: 7/6/2016]